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November 18, 2020

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

> Re: IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION
> Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Please accept this supplemental brief on behalf of the Plaintiffs, in further and continued opposition to Teva's motion regarding the use of TAR 2.0 to eliminate Teva's document review obligations, contrary to the ESI protocol and the two orders establishing agreed search terms.

This matter has been discussed with the Court many times, and has been formally argued, most recently on November 11, 2020.[1] Plaintiffs submit that the record is already dispositive of the motion. Teva seeks to establish a dangerous precedent which would ultimately permit any

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[1]   In order to bring the Court up to date, Plaintiffs advise that no communications have been received from Teva regarding this issue since the conclusion of argument on November 11, 2020.

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producing party to modify agreed and Court Ordered ESI search methodology at any stage of the review and production process, and to unilaterally alter the methodology according to its own self-selected protocol, without any consequences. There is no precedent allowing such a radical, unilateral departure from a fully agreed and ordered process.

Teva has only itself to blame. Teva's lack of due diligence began with its refusal to test and sample proposed search terms, and refusal to collaborate with Plaintiffs on the results, before the search terms were agreed to. Teva's claim that it could not have done so before all of the custodians were agreed to is obviously inaccurate. Testing is routinely run on the custodial sets of those custodians who are clearly going to be included. Teva certainly could have easily identified clearly needed custodians, including those that Teva identified at the outset of the discussions with the Plaintiffs to identify the group of custodians to be searched. Teva then belatedly requested modifications to the search terms, and once again agreed to a set of search terms. Then, only after agreeing to this revised set of search terms, Teva belatedly announced on July 1, 2020, its "potential" use of TAR to reduce document review costs that Teva had already agreed to multiple times – an announcement made after Teva had already started applying its TAR system without any prior notice to Plaintiffs.

During the November 11, 2020 oral argument, Teva could not credibly defend its lack of diligence or good judgment in the handling of this situation. For example, after agreeing without objection to the initial and revised search terms, Teva almost immediately reversed course to apply a TAR review to "potentially" narrow the set of documents to be reviewed for production. Plaintiffs were not informed of this change until after TAR had been initiated, and Teva's suggestion that it initiated the TAR review solely in order to benefit Plaintiffs is simply not

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credible. TAR is not free – it has a cost for implementation by the vendor and most vendors charge

a significant premium to implement TAR versus simply hosting the underlying documents. It is

implausible for Teva to contend that it agreed to accept this cost without the expectation that this

cost would lead to a narrowing of documents that it would eventually review. This was a violation

of the ESI protocol, as Teva was required to meet and confer first – as soon as it contemplated that

TAR might be implemented to narrow the document review set, with the Court as a backstop to

the extent there was disagreement on the terms.

Despite this, Plaintiffs worked in good faith with Teva to negotiate a protocol that could

relieve Teva's stated financial concerns while protecting Plaintiffs' need for robust validation to

attempt to ensure that relevant documents would be produced. Teva then refused to agree to

implementation of the validation protocol accepted by the Plaintiffs based on considerations

outside its stated concerns about this litigation; because it did not want to allow the protocol to be

filed on ECF and thus create a "bad precedent" due to its agreement to produce a carefully selected

audit sample of thousands of "non-responsive" documents to Plaintiffs. That was the only reason

that the protocol was not implemented.

Ironically, Teva's concerns were misplaced, since the provision of un-reviewed documents

to Plaintiffs would have actually been in line with established law. Parenthetically, Teva and its

expert have repeatedly misstated the law. Another example of Teva's misstatements of the law is

Teva's insistence that production of documents not reviewed for relevance never occurs, except

perhaps in a punitive situation. The law is obviously to the contrary. *See In Re: 3M Combat Arms*

Earplug Products Liab. Litig., No. 3:19-md-2885 (N.D. Fla. 2019) (Exhibit A hereto); *In re*

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Actavis Holdco U.S. Inc., No. 19-3549, 2019 WL 8437021, at *1 (3d Cir. Dec. 6, 2019) (Exhibit B hereto).

Finally, Teva inexplicably failed to implement the validation protocol agreed to by the Plaintiffs when Teva went ahead and unilaterally applied its own protocol to narrow the review set anyway, without notice to Plaintiffs, in violation of the ESI protocol. These facts are egregious, and preclude the relief sought by Teva.

Teva's attempt to play down or obscure the substantial protections built into the negotiated protocol, but not utilized by Teva, is also very telling. It is helpful to reflect back on some foundational facts. Teva's TAR system ranks documents on a scale from very likely to be relevant to less likely to be relevant, based upon their similarity (or lack thereof) to other documents which have previously been manually marked relevant. When Teva discusses the "null set," it is really talking about those documents that the system has determined are dissimilar to those previously coded by manual reviewers to be relevant. Thus, in any large document production, such as the one here, there is going to come a point in time where the system has exhausted those documents that it calculates are similar to those previously marked as relevant, and thus, has ranked lower. This does not mean, however, that the system actually thinks those documents are irrelevant – the system is incapable of making such a value judgment. Rather, the system is just indicating the remaining documents do not exhibit those characteristics (such as words, phrases, etc.) similar in nature to those previously marked as relevant.

The importance of training and robust validation in which the Plaintiffs have input is to assure the parties that there are not documents with dissimilar characteristics from the ones marked relevant by the reviewers that are, in actuality, also relevant. A significant problem with Teva's

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unilateral approach in violation of the ESI protocol is that Plaintiffs had no input or visibility into

the process of review, nor did Plaintiffs have access to the leftover set of documents. And Teva's

admission that the TAR system was only 92% effective means that nearly 10% of the documents

in the so-called "null set" are actually relevant and would need to be produced.

In this connection, at the November 11, 2020 hearing, the Court summarized provisions of

the protocol agreed to by the Plaintiffs that were not implemented by Teva when it went forward.

Review of the draft protocol reveals the full scope of important protections not implemented by

Teva. For example, during the course of the November 11, 2020 argument, Teva's counsel stated

that the core discovery documents were utilized to educate the system. That statement is

inaccurate. During the parties' discussions, Teva explicitly confirmed that the core discovery

documents had **not** been utilized. The proof for this is found in the protocol agreed to by Plaintiffs,

which explicitly provided that Teva would use the core discovery documents as "training

examples" at the outset. That provision would not have been included if this had already occurred.

In fact, the protocol provided for Plaintiffs to provide up to 100 additional documents for training

of the system, including Teva documents and potentially documents from other manufacturers.

These are just two of the many provisions that Plaintiffs had staked out as essential in the protocol,

but which were not ultimately implemented.

As conceded by Teva during oral argument, Plaintiffs were given no input into the process

that was followed by Teva after it unreasonably walked away from the agreement that would have

given Teva the relief it said it needed. To be clear, as set forth above, Teva agreed to the entire

protocol, including providing an validation audit sample of thousands of documents to the

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Plaintiffs for independent analysis. The sole and final sticking point was the filing of the protocol

on the docket, not the substantive contents of the protocol.

Ultimately, Teva's position that it was justified in following its own unilateral path is

directly contrary to the body of case law in this area (and the ESI protocol) requiring transparency

and cooperation where TAR of any nature is proposed to be used for the purpose of review and

production of documents, including the cases relied on most heavily by Teva:[2]

In *In re Biomet M2a Magnum Hip Implant Products Liab. Litig.*, the Defendant had already

implemented an extensive review and production protocol before the MDL was established, as

discovery was already proceeding in various federal courts. No. 3:12-md-2391, 2013 WL 1729682

*1, *3 (N.D. Ind. April 18, 2013) (Exhibit D hereto). Plaintiffs sought a more detailed validation

protocol than the defendant had employed. The Court did not require the defendant to go back to

square one, but emphasized that the defendant had agreed to participate in an ongoing meet and

confer to expand the search terms as needed, and had agreed to produce "the non-privileged

documents included in the statistical sample....so the steering committee can verify that Biomet is

producing the relevant documents." *Id.* at *1. In other words, the audit sample of "non-

responsive" documents was to be provided to the plaintiffs to validate the TAR process that had

been employed.

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[2]   During the November 11, 2020 oral argument Teva's counsel cited yet another case that
does not support its position. The Order entered in *Global Aerospace, Inc. v. Landow Aviation,
LP* simply provides for the use of predictive coding. 2012 WL 1431215 (Circuit Court of Loudoun
Cty., April 23, 2012) (Exhibit C hereto). There is no discussion of any analysis, nor is there any
suggestion that the issues now before this Court were determined in that case.

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In *In re Broiler Chicken Antitrust Litig.*, the ESI Search Methodology Order submitted by Teva, the producing party was required to make disclosures, and the requesting party was given an opportunity to communicate concerns and propose additional exemplar documents for training the system. No. 1:16-cv-08637 (E.D. Ill. January 13, 2018) (Exhibit E hereto). In Section II A 4, the protocol provided: "**Cooperation**: the parties agree to work together in good faith to resolve any differences that they may have over the producing Party's use of TAR/CAL and its processes, recall, and validation proposals...." with any disputes to be submitted to the Special Master and the Court. Instead, Teva employed a unilateral protocol with no input from or involvement of Plaintiffs.

In *Bridgestone Americas, Inc. v. I.B.M. Corp.*, the Court allowed the plaintiff to transition from a search terms methodology to add TAR to the process, but only with the following caveats: "Consequently, openness and transparency in what Plaintiff is doing will be of critical importance. Plaintiff has advised that they will provide the seed documents they are initially using to set up predictive coding. The Magistrate Judge expects full openness in this matter…. The Magistrate Judge expects the parties to communicate, through their attorneys and experts and companies doing the work, on a frequent and open basis." No. 3:13-1196, 2014 WL 4923014, at *1 (M.D. Tenn. July 22, 2014) (Exhibit F hereto). Again, despite knowing this caselaw, Teva unilaterally bypassed open communication and transparency, and simply announced what it had done and the result it demanded.

Similarly, in *City of Rockford v. Mallinckrodt Ard Inc.*, the Court imposed a similar provision to that in place here: "Prior to using...[TAR].., for the purpose of identifying or culling the documents to be reviewed or produced, the producing party will notify the opposing party with

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ample time to meet and confer in good faith regarding a mutually agreeable protocol for the use of such technologies or alternatives...," and specified various validation focused issues to be included in that discussion. No. 3:17-cv-50107, 7 (N.D. Ill. August 14, 2018) (Exhibit G hereto).

Finally, in *Rio Tinto PLC v. Vale S.A. et al.*, the Court was addressing a very different situation than here. 306 F.R.D. 125 (S.D.N.Y. 2015). The parties were both commercial entities, both agreed to a TAR protocol, both parties used the same protocol from the outset, and the parties agreed to share seed sets of documents, and to allow the requesting party to obtain quality control reports during the reviews. The Court cited to *In re Actos*, 2012 WL 7861249 (W.D. La. July 27, 2012), described as follows: "the parties' protocol had 'experts' from each side simultaneously reviewing and coding the seed set." *Rio Tinto*, 306 F.R.D. at 128. That case is obviously quite different factually, but still illustrates the consistent theme – cooperation, transparency, and substantial input from the receiving party is critical. Here, Teva chose to go it alone, and thus is not entitled to the drastic relief requested.

For the foregoing reasons, and for the reasons presented in Plaintiffs' prior submissions and during discussion with the Court, Teva's motion should be denied. The words of Judge Cavanaugh ring true once again: "However, Defendants are cautioned that the Special Master will not look favorably on any future arguments related to burden of discovery requests, specifically cost and proportionality, when Defendants have chosen to utilize the custodian-and-search term approach despite wide acceptance that TAR is cheaper, more efficient and superior to keyword searching." *In re Mercedes-Benz Emissions Litig.*, No. 2:16-cv-881, 2020 WL 103975, at *2 (D.N.J. Jan. 9, 2020) (Exhibit H).

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Teva should be required to manually review the full set of custodial documents captured by the search terms, or to produce the proposed non-reviewed set to the Plaintiffs. It is too late, and too much time and effort has been expended on this issue, for Teva to switch gears and seek to apply another protocol, or to seek another alternative. In addition, in light of the massive waste of time and resources during the July/August 2020 discussions, Teva should be sanctioned in an appropriate amount in the Court's discretion.

Respectfully,

Adam M. Slater